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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09-713,994	11/16/2000	James Keddle	MBI-0022	7536

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WILEY REIN & FIELDING LLP  
Intellectual Property Department  
1776 K Street NW  
Washington, DC 20006

EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/713,994

Applicant(s)

KEDDIE ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-8, 13, 14, 25 and 26, drawn to a transgenic plant with a modified trait, an isolated recombinant polynucleotide, a cloning or expression vector comprising said polynucleotide, and a method of making said transgenic plant, classified in class 800, subclass 301, for example.
  - II. Claims 9 and 10, drawn to a composition produced by incubating one or more polynucleotides, classified in class 536, subclass 23.1, for example.
  - III. Claim 11, drawn to an isolated or recombinant polypeptide, classified in class 530, subclass 370, for example.
  - IV. Claim 12, drawn to a plant ectopically expressing an isolated polypeptide, classified in class 800, subclass 298, for example.
  - V. Claims 15-17, drawn to a method of identifying a factor that is modulated by or interacts with a polypeptide comprising expressing a polypeptide in a plant, classified in class 435, subclass 6, for example.
  - VI. Claim 18, drawn to a method of identifying a molecule that modulates activity or expression of a polynucleotide or polypeptide of interest comprising placing said molecule in contact with a plant, classified in class 800, subclass 278, for example.

- VII. Claims 19 and 20, drawn to an integrated system, computer or computer medium, classified in class 700, subclass 96, for example.
- VIII. Claims 21-24, drawn to a method of identifying a sequence similar to *or* homologous to one or more polynucleotides, classified in class 703, subclass 11, for example.
- IX. Claim 27, drawn to a plant lacking a specific nucleotide sequence, classified in class 800, subclass 323.1, for example.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated recombinant polynucleotide of Group I can be used to make a materially different product than the composition of Group II, such as a transgenic plant.
- 3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the transgenic plant and isolated recombinant polynucleotide are structurally, compositionally and functionally distinct from the isolated or recombinant polypeptide of Group III.

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4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated recombinant polynucleotide of Group I can be used to make a materially different product than the plant of Group IV, such as a transgenic plant that has a modified trait.

5. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic plant of Group I can be used in a materially different method than the method of identifying a factor of Group V, such as the method of identifying a molecule that modulates activity or expression of a polynucleotide or polypeptide of interest of Group VI.

6. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic plant of Group I can be used in a materially different method than the method of identifying a molecule that modulates activity or expression of a polynucleotide or

polypeptide of interest of Group VI, such as the method of identifying a factor that is modulated by or interacts with a polypeptide of Group V.

7. Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the integrated system of Group VII cannot be used to make the transgenic plant of Group I, and is functionally, compositionally and structurally different from the isolated recombinant polynucleotide of Group I.

8. Inventions I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of Group VIII requires information to practice the method and the method of making a transgenic plant of Group I requires a composition of matter, that being a polynucleotide molecule.

9. Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the plant lacking a nucleotide sequence of Group IX does not require the isolated recombinant polynucleotide of Group I.

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10. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the composition of Group II does not require the isolated or recombinant polypeptide of Group III.

11. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the plant of Group IV is compositionally, structurally and functionally distinct from the composition of Group II.

12. Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the composition of Group II is not required to practice the method of Group V.

13. Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the composition of Group II is not required to practice the method of Group VI.

14. Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the composition of Group II is structurally, functionally and compositionally distinct from the integrated system of Group VII.

15. Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the composition of Group II cannot be used in the method of Group VIII.

16. Inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the composition of Group II is structurally, functionally and compositionally distinct from the plant of Group IX.

17. Inventions III and IV-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the isolated or recombinant polypeptide cannot be used in the method of Group V, VI or VIII, and is structurally, functionally and compositionally distinct from the plant of Group IV or IX and the integrated system of Group VII.



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18. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of identifying a factor of Group V can be practice<sup>d</sup><sub>^</sub> using a different plant from that of Group IV, such as a plant that naturally comprises the required polynucleotide.

19. Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of identifying a molecule of Group VI can be practice<sup>d</sup><sub>^</sub> using a different plant from that of Group IV, such as a plant that naturally comprises the required polynucleotide.

20. Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the plant of Group IV is structurally, functionally and compositionally distinct form the integrated system of Group VII.

21. Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the plant of Group IV cannot be used in the method of Group VIII.

22. Inventions IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the plant of Group IV and the plant of Group IX are structurally, functionally and compositionally distinct.

23. Inventions V and VI-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of identifying a factor of Group V has different method steps, different starting materials and different end products than the method of Group VI or VIII, and the method of Group V cannot be used to produce the integrated system of Group VII or the plant of Group IX.

24. Inventions VI and VII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of identifying a molecule of Group VI has different method steps, different starting materials and different end products than the method of identifying a sequence of Group

VIII, and the method of Group VI cannot be used to produce the integrated system of Group VII or the plant of Group IX.

25. Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the integrated system of Group VII can be used in materially different process than the method of Group VIII, such as a database.

26. Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the integrated system of Group VII is structurally, compositionally and functionally distinct from the plant of Group IX.

27. Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of Group VIII cannot be used to produce the plant of Group IX.

28. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and would

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require distinct searches of the art, restriction for examination purposes as indicated is proper.

29. In addition, **Applicant is required to elect** one nucleic acid sequence to be examined in conjunction with the election of either Group I, II, III, IV, V, VI or IX. The Patent and Trademark Office recently published its policy for the examination of patent applications that claim large numbers of nucleotide sequences in the Official Gazette, 1192 O.G. 68 (November 19, 1996). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such nucleotide is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR § 1.141. In establishing the new policy, the Commissioner has partially waived the requirements of 37 CFR § 1.141et seq. and permits a reasonable number of such nucleotide sequences to be claimed in a single application. It has been determined that normally ten sequences constitute a reasonable number for examination purposes. The Official Gazette Notice of November 19, 1996 is one that permits the examiner to waive restriction to no more than one invention. Since 1996, databases and resource allocations at the PTO have changed and the examination of 10 sequences on the merits in the instant application would present a burden on PTO resources. Additionally, it is noted that one nucleotide and one amino acid sequence is within the

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O.G. notice range of "up to ten" sequences. This election is not to be construed as an election of species.

30. Applicant is advised that the reply to this requirement to be complete within one month (not less than 30 days) must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

31. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

David H. Kruse, Ph.D.  
9 April 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~180~~ 1638

